BRAZIL

MEDECINS SANS FRONTIERES
DOCTORS WITHOUT BORDERS

LENACAPAVIR ACCESS SNAPSHOT


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Lenacapavir is a highly effective, long-acting HIV prevention option administered only twice a year. It could be a game-changing tool, but only if it reaches the people who need it.

This comes at a critical moment: Latin America is one of the few regions where new HIV infections continue to rise[1], while Brazil continues to record a high burden of HIV, with nearly 40,000 HIV diagnoses in 2024 alone[2]. These figures are a stark reminder that existing prevention options are still not reaching everyone who needs them, especially key populations and young people who remain disproportionately affected.

Yet access to lenacapavir is currently being determined by the decisions of a single company – Gilead - rather than by public health needs. High prices, patent barriers, exclusion from generic licensing agreements and limited supply risk keeping this highly effective prevention tool out of reach for most people who could benefit from it. These barriers can — and must — be addressed through concrete public interest action.

1. UNAIDS. Latin America — Regional profile — 2025 Global AIDS Update. 2025. Available at: https://www.unaids.org/sites/default/files/2025-07/2025-global-aids-update-latam.pdf

2. Ministério da Saúde. Boletim Epidemiológico de HIV e Aids - Número Especial | Dez. 2025. Brasília: Ministério da Saúde; 2025. Available at: https://www.gov.br/saude/pt-br/centrais-de-conteudo/publicacoes/boletins/epidemiologicos/especiais/2025/boletim-epidemiologico-de-hiv-e-aids-numero-especial-dez-2025.pdf

BRAZIL'S REGIONAL RELEVANCE

Brazil has the largest public HIV program in Latin America and could generate substantial demand for affordable lenacapavir.

Brazil approved lenacapavir for HIV prevention in January 2026, making decisions on price, incorporation and procurement immediately relevant.

Brazilian communities participated in the clinical research that supported lenacapavir's approval.

Brazil has a strong history of community and civil society mobilization to advance access to HIV prevention and treatment, including by challenging patent monopolies and advocating for public-interest measures.

Brazil has previously used compulsory licenses and other public-interest measures to reduce the price of HIV medicines, produce generics, and expand access.

The country has significant pharmaceutical manufacturing capacity, including official laboratories with a public health mandate, that could produce generic versions of lenacapavir.

A successful access pathway in Brazil could provide an important model for other countries in the region.

1. REGULATORY STATUS AND AVAILABILITY THROUGH THE PUBLIC HEALTH SYSTEM (SUS)

In January 2026, ANVISA, Brazil's national medicines regulatory agency, approved Gilead's lenacapavir for HIV prevention[3]. Gilead is currently the only manufacturer authorized to market lenacapavir in the country.

However, Câmara de Regulação do Mercado de Medicamentos (CMED), the national medicines price regulator, has not yet set the maximum price at which the medicine can be sold following Gilead's price proposal. For lenacapavir to be provided through the public health system (SUS), it must also be assessed by the Comissão Nacional de Incorporação de Tecnologias no Sistema Único de Saúde (CONITEC), the national health technology assessment body, and formally incorporated by the Ministry of Health—a decision that will also depend on the price.

3. Agência Nacional de Vigilância Sanitária (ANVISA). Sunlenca® (lenacapavir): nova indicação. Publicação no DOU: 12/01/2026. Available at: https://www.gov.br/anvisa/pt-br/assuntos/medicamentos/novos-medicamentos-e-indicacoes/sunlenca

2. PRICE AND AFFORDABILITY

Price can be a major barrier to access.

Gilead holds the monopoly on lenacapavir and is currently the only company selling it worldwide. Gilead's proposed price in Brazil is confidential, but Brazilian Ministry of Health representatives indicated that it is dozens of times higher than the approximately USD 40 annual price expected for licensed generics.

The government has indicated that it could pay around USD 400 per person per year for incorporation into the public health system. The comparison below illustrates the enormous gap between monopoly pricing and the potential cost of generic supply — and how this can make lenacapavir unaffordable in Brazil. It also shows how many people could be reached with the same budget at different price levels.

PRICE POINT	ANNUAL PRICE / PERSON	PEOPLE REACHED
Gilead's US list price [4]	USD 28,000	1
Reported reference price for incorporation into the public health system (SUS) [5]	USD 400 (~2× the price of oral PrEP)	70
Announced price for licensed generics [6]	USD 40	700

4. UNAIDS. UNAIDS urges Gilead to drop price of new HIV prevention medicine in the United States and ensure sustainable access for low- and middle-income countries. 18 June 2025. Available at: https://www.unaids.org/en/resources/press-centre/pressreleaseandstatementarchive/2025/june/20250618_lenacapavir

5. Source: Meeting with representatives of the Brazilian Ministry of Health, 2026.

6. Unitaid, CHAI, and Wits RHI enter into a landmark agreement with Dr. Reddy's to make HIV prevention tool lenacapavir affordable in LMICs. 24 September 2025. Available at: https://unitaid.org/news-blog/lenacapavir-for-hiv-prevention/

3. SUPPLY AND AVAILABILITY

Patents can limit medicine supply and keep prices high by restricting generic competition.

Because Gilead holds patents on lenacapavir, generic manufacturers generally need a license to produce and supply generic versions in countries where those patents apply. Gilead has signed voluntary licensing agreements with selected manufacturers to supply generic lenacapavir in 120 countries[7]. However, Brazil is excluded from these licenses, despite having hosted clinical trials that supported lenacapavir's approval.[8]

Gilead holds two layers of granted compound-level patent protection on lenacapavir in Brazil. The first could remain in force until 2034 and the second until 2037[9]. The later compound patent may be vulnerable to invalidation if lenacapavir was already disclosed in the earlier broader (Markush) patent.

Unless the patents are invalidated[10] or overridden, Brazil will remain dependent on Gilead as the only supplier until they expire.

Brazil has legal tools to address this situation. Patents that may not meet the country's legal requirements can be challenged and invalidated. The government can also issue a compulsory license including on public-interest grounds, allowing production or importation by other manufacturers without Gilead's authorization.

7. Gilead sciences. Gilead signs royalty-free voluntary licensing agreements with six generic manufacturers to increase access to lenacapavir for hiv prevention in high-incidence, resource-limited countries. 2 October 2024. Available at: https://www.Gilead.Com/news/news-details/2024/gilead-signs-royalty-free-voluntary-licensing-agreements-with-six-generic-manufacturers-to-increase-access-to-lenacapavir-for-hiv-prevention-in-high-incidence-resource-limited-countries

8. Médecins Sans Frontières Access Campaign. Gilead's voluntary license on lenacapavir: key limitations of the license and recommendations to improve access. 3 July 2025. Available at: https://msfaccess.Org/gileads-voluntary-license-lenacapavir-key-limitations-license-and-recommendations-improve-access

9. Instituto nacional da propriedade industrial (INPI). Busca de processos — base de patentes. Patent applications br112015021027, br112018071678 and br122020001791. Available at: https://busca.Inpi.Gov.Br/pepi/

10. In Brazil, patent invalidation may be sought through administrative or judicial proceedings. Administrative invalidation proceedings may be initiated ex officio by INPI or at the request of any person with a legitimate interest within six months of the patent grant, pursuant to article 51 of law no. 9,279/1996. For the patents already granted on lenacapavir, this deadline has expired.

3. SUPPLY AND AVAILABILITY

Brazil's experience with compulsory licensing

For several years, Brazil used the credible possibility of issuing compulsory licenses to negotiate lower prices for patented HIV medicines. This strategy was strengthened by the country's public pharmaceutical manufacturing capacity, which could provide estimates of generic production costs and a potential source of supply.

In 2007, after price negotiations with Merck Sharp & Dohme failed, Brazil issued a compulsory license for efavirenz. The measure reduced the price by almost 70%, and saved USD 103.5 million in public resources between 2007 and 2011 through the purchase of the generic version. These savings helped Brazil sustain and expand universal access to HIV treatment. The number of people receiving efavirenz increased by about 55% after the compulsory license was issued.[11]

Gilead has also filed other patent applications related to lenacapavir, including a standalone oral medication not included in the existing voluntary licenses for the production of generic lenacapavir. While these new applications are not expected to block generic versions of the currently approved regimen - including the injectable formulation and the oral formulation needed for regimen initiation - they should be monitored to prevent new patents from delaying access to future lenacapavir-based regimens. In Brazil, one relevant application that includes a modified version of lenacapavir (prodrug) is still pending[12]. It could be subject to pre-grant opposition (observations), a mechanism that allows any interested party to submit information to INPI to support patent examination[13]. This mechanism does not require a lawyer, but it is subject to payment of the applicable INPI fee.

However, for these measures to be effective, generic versions of lenacapavir must be available for supply in Brazil. Brazil is currently excluded from Gilead's voluntary licenses and cannot purchase lenacapavir from the six authorized generic manufacturers, which are also prohibited from supplying excluded countries even where no patent barriers exist.

Moreover, current supply commitments aim to reach around 3 million people through 2028[14], while the global need for PrEP exceeds 20 million[15]. Therefore, even if Brazil is included in the licenses, supply may remain insufficient to meet the country's needs.

Regardless of any licensing agreement with Gilead, Brazil should support the development of additional sources of lenacapavir to ensure a secure and sustainable supply at affordable prices. The country has significant pharmaceutical manufacturing capacity, including official laboratories with a public health mandate whose role should be strengthened. Brazil's patent law includes research and Bolar exceptions that allow manufacturers to conduct research and undertake the activities needed to obtain regulatory approval while patents remain in force, paving the way for immediate market entry upon patent expiry, invalidation, or the issuance of a compulsory license.

Finally, because lenacapavir is a long-acting injectable, generic manufacturers may need to provide additional product-specific evidence beyond the usual requirements. ANVISA should therefore engage early with potential manufacturers and clarify the requirements for approving generic versions of lenacapavir.

11. Silva FVN, Hallal R, Guimarães A. Compulsory License and Access to Medicines: Economic Savings of Efavirenz in Brazil. Presented at the XIX International AIDS Conference, Washington, DC, 22–27 July 2012. Video recording available on YouTube: https://www.youtube.com/watch?v=-FlwhjANOuvo

12. INPI. Busca de processos — Base de Patentes. Search patent application BR112024010162, corresponding to WO2023102239 / PCT/US2022/051734. Available at: https://busca.inpi.gov.br/pePI/

13. It is worth noting that civil society organizations participating in the Working Group on Intellectual Property (GTPI), coordinated by the Brazilian Interdisciplinary AIDS Association (ABIA), have already submitted observations to INPI to support the examination of this patent application.

14. The Global Fund. Global Fund and U.S. Expand Commitment to Long-Acting HIV Prevention as Country Rollout of Lenacapavir Accelerates. 14 April 2026. Available at: https://www.theglobalfund.org/en/updates/2026/2026-04-14-us-global-fund-expand-commitment-long-acting-hiv-prevention-country-rollout-lenacapavir-accelerates/

15. UNAIDS. 2025 Global AIDS Update: AIDS, crisis and the power to transform. Geneva: UNAIDS; 2025. Available at: https://www.unaids.org/sites/default/files/2025-07/2025-global-aids-update-JC3153_en.pdf

3. SUPPLY AND AVAILABILITY

LEGAL TOOL PRE-GRANT OPPOSITION (THIRD-PARTY OBSERVATIONS)

WHAT IT IS & WHAT IT CAN DO	LEGAL BASIS	WHO CAN USE IT	WHEN	COST
A submission of documents and information to INPI to support patent examination before it is granted. It can help prevent the grant of a patent that does not meet patentability requirements.	Article 31 of Law No. 9,279/1996	Any interested person or organization. A lawyer is not required.	After publication of the patent application and until the end of examination.	Applicable INPI filing fee[16]

LEGAL TOOL POST-GRANT OPPOSITION (JUDICIAL INVALIDITY ACTION)

WHAT IT IS & WHAT IT CAN DO	LEGAL BASIS	WHO CAN USE IT	WHEN	COST
A court action seeking the invalidation of all or part of a patent.	Articles 56–57 of Law No. 9,279/1996	The patent office (INPI) or any person or organization with a legitimate interest. A lawyer is required.	At any time while the patent remains in force.	Court fees and legal costs vary according to the case.

LEGAL TOOL RESEARCH EXCEPTION

WHAT IT IS & WHAT IT CAN DO	LEGAL BASIS	WHO CAN USE IT	WHEN	COST
Allows acts involving a patented invention for experimental purposes related to scientific or technological studies or research	Article 43(II) of Law No. 9,279/1996	Researchers, manufacturers and other persons or organizations conducting experimental activities.	While the patent remains in force.	No license or remuneration to the patent holder (royalties) are required; ordinary research costs apply.

LEGAL TOOL COMPULSORY LICENSE (PUBLIC INTEREST)

WHAT IT IS & WHAT IT CAN DO	LEGAL BASIS	WHO CAN USE IT	WHEN	COST
Government authorization to produce or import a generic version of a patented product without the patent holder's consent.	Article 71 of Law No. 9,279/1996 and Decree No. 3,201/1999.	The federal Executive Branch grants the license after a public interest or national or international emergency has been declared by law or federal executive act. Civil society can advocate for government action.	At any time while the patent remains in force.	Royalties paid by the government or the licensee.

LEGAL TOOL BOLAR EXCEPTION

WHAT IT IS & WHAT IT CAN DO	LEGAL BASIS	WHO CAN USE IT	WHEN	COST
Allows activities involving a patented invention solely to generate the information, data and test results required for regulatory approval. This can accelerate generic entry once the patents expire or are otherwise overcome.	Article 43(VII) of Law No. 9,279/1996	Generic manufacturers and other persons or organizations preparing a regulatory submission.	While the patent remains in force.	No license or royalties are required; development, testing and regulatory costs apply.

16.INPI. Schedule of Fees for Services Provided by INPI, service code 279 — Third-party observations to support substantive examination. Available at: https://www.gov.br/inpi/pt-br/servicos/patentes/custos-e-pagamento-de-retribuicao/custos-e-pagamento-de-retribuicao

4. PRIORITY ACTIONS FOR SUSTAINABLE ACCESS

Access to lenacapavir in Brazil will depend on overcoming several interconnected barriers: an unaffordable price, patent-based monopoly and limited global supply. To help overcome these barriers:

People who could benefit from lenacapavir cannot continue waiting while access depends on a single company's commercial decisions on pricing, licensing and supply. Brazil should act now to ensure this prevention option is affordable and available at scale through the public health system, in line with people's needs.

We cannot allow history to repeat itself: people's health and access to HIV prevention must take precedence over commercial interests and pharmaceutical company profits.

GILEAD SHOULD

- Offer Brazil a transparent and affordable price that allows large-scale provision through the public health system.
- Expand its voluntary licenses to include all middle-income countries, including Brazil, or, at a minimum, allow licensees to supply countries where no patent barriers exist or where patent barriers have been overcome through legal mechanisms.
- Increase the number and geographic diversity of licensed manufacturers, including Brazilian manufacturers, to expand global supply.

THE BRAZILIAN GOVERNMENT SHOULD:

- Conduct transparent price negotiations with Gilead and disclose proposed prices, supply volumes, delivery timelines and other terms needed to assess whether any agreement is compatible with public health needs.
- Ensure rapid price and health technology assessments, while maintaining rigorous scrutiny of affordability and public health impact.
- Have the relevant government bodies assess lenacapavir patent applications and granted patents and, where they do not meet patentability requirements, take action to prevent their grant or seek their invalidation.
- Apply rigorous pharmaceutical patent examination guidelines and, where necessary, revise them to prevent the grant of excessively broad claims, such as Markush claims, and claims covering modifications of known products, such as prodrugs, that do not meet patentability requirements.
- Issue compulsory licenses to enable the production, importation and supply of affordable generic lenacapavir.
- Encourage and support potential Brazilian manufacturers, particularly official laboratories, in using the research and Bolar exceptions to conduct research, develop generic lenacapavir and prepare regulatory submissions while patents remain in force.
- Provide early regulatory guidance for generic lenacapavir approval.
- Use public procurement to create predictable demand for generic lenacapavir and support sustainable, geographically diverse production in Brazil, across the region and internationally.

COMMUNITIES AND CIVIL SOCIETY ORGANIZATIONS SHOULD CONTINUE TO:

- Demand transparency on prices, supply commitments, licensing terms and government negotiations with Gilead.
- Contribute to the analysis of lenacapavir patents and, where appropriate, initiate or support patent oppositions.
- Advocate for the use of compulsory licensing and other public-interest measures to facilitate affordable, sustainable supply of lenacapavir.
- Hold Gilead and the government accountable for ensuring affordable and sustainable access, particularly given Brazil's participation in the clinical trials that supported lenacapavir's approval.